510(K) SUMMARY

August 29, 2008

Submitted By: NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED Mini Ghost PTA Catheter; 21 CFR 870.1250 – Percutaneous Catheter

Predicate Devices: NuMED Mini Ghost PTA Catheter

Device Description: The Mini Ghost PTA Catheter is a coaxial catheter indicated for PTA of small vessels outside of the heart. This catheter is not intended for use in the coronary arteries. The catheter consists of a 3.5F polyamide outer shaft with a distally mounted balloon. The catheter terminates proximally in a bifurcated Y sleeve with separate extensions for the balloon and the guidewire. The inner tubing extends through the balloon and accommodates a 0.018" guidewire. The lumen has radiopaque platinum marker bands under the balloon shoulders for placement using fluoroscopy. The catheter balloon diameter is stamoed onto the Y sleeve and the balloon extension is labeled with balloon diameter x balloon length x introducer size x shaft size x usable length x guidewire size and the catheter lot number. The catheter is packaged in a polyethylene sheath and is double packed in two heat sealed Tyvek pouches.

Biocompatibility Testing:

The materials used in the NuMED Mini Ghost PTA Catheter are the same as those used in the already cleared Mini Ghost PTA Catheter (510(k) #K051343) and Z-MED Catheter (K931009) which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.

Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing:

All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc. Copies are included as an attachment.

Intended Use:

This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

Comparison Information:

MODEL:	NUMED MINI GHOST PTA CATHETER	NUMED MINI GHOST PTA CATHETER - ADDT'L LENGTHS
Indications:	▪ This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**	▪ This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**
Shaft Size:	3.5F	3.5F
Guidewire Size:	0.018"	0.018"
Usable Length:	40cm – 150cm	40cm – 150cm
Balloon Diameter:	2mm – 6mm	2mm – 6mm
Balloon Length:	2cm – 10cm	1cm – 10cm
Materials:	Shaft: Pebax Balloon: PES2 Image Band: Platinum	Shaft: Pebax Balloon: PES2 Image Band: Platinum
Construction:	Coaxial construction with distally mounted non-compliant balloon.	Coaxial construction with distally mounted non-compliant balloon.

RISK ANALYSIS

Copies of The Risk Reports are attached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

NuMED, Inc.
c/o Ms. Nichelle LaFlesh
Regulatory Affairs Manager
2880 Main Street
Hopkinton, NY 12965

Re: K082524
Trade/Device Name: Mini Ghost PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: August 29, 2008
Received: September 2, 2008

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082524

Device Name: **Mini Ghost PTA Catheter**

Indications For Use:

- This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K082524

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